

DO NOT ENTER: /K.S.O./

026086-047.29US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:

Applicant: **Moti Harel**

Application No.: 10/534,090

Date Filed: February 8, 2006

Title: NUTRACEUTICALS AND METHOD OF FEEDING AQUATIC ANIMALS

Docket No.: 026086-047.29US

Examiner: Kevin S. Orwig

Art Unit: 1611

Conf. No.: 2449

Customer No.:

24239

**RESPONSE TO AUGUST 31, 2010 FINAL OFFICE ACTION IN U.S. PATENT APPLICATION
NO. 10/534,090**

Mail Stop AF
Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

Sir:

In response to the August 31, 2010 Final Office Action issued for the above-identified application, Applicant makes the following remarks and amends the claims as follows:

In the claims

1-86. (canceled)

87. (Currently amended) An animal feed composition comprising a particle ranging in size from the about 100 μm to about 1 cm, wherein the particle is formulated to begin dissolving within the pH range of an animal's foregut, wherein ~~such~~ the particle comprises alginate and a starch-emulsifier complex, wherein the alginate comprises from about 0.5 to about 2.0 percent by wet weight of the particle, the emulsifier comprises a ratio to the starch from about 1:10 to about 10:1, and the starch-emulsifier complex is partially or completely insoluble in water.

88. (Previously presented) The composition of claim 87, wherein the particle comprises from about 0.5 to about 1.0 percent alginate by wet weight of the particle.

89. (Previously presented) The composition of claim 88, wherein the particle comprises about 1.0 percent alginate by wet weight of the particle.

90. (Previously presented) The composition of claim 87, wherein the starch comprises from about 1.0 to about 4.0 percent by wet weight of the particle.

91. (Previously presented) The composition of claim 90, wherein the starch comprises about 2.0 percent by wet weight of the particle.

92. (Previously presented) The composition of claim 87, wherein the emulsifier and starch are present in an emulsifier to starch ratio from about 1:5 to about 5:1.

93. (Previously presented) The composition of claim 92, wherein the emulsifier and starch are present in an emulsifier to starch ratio from about 1:4 to about 2:1.

94. (Previously presented) The composition of claim 92, wherein the emulsifier and starch are present in an emulsifier to starch ratio of about 1:2.

95. (Previously presented) The composition of claim 87, wherein the starch is selected from the group consisting of modified starch, high amylose starch, and combinations thereof, and wherein the starch complexes with the emulsifier in an alkali solution.
96. (Previously presented) The composition of claim 87, further comprising a bioactive agent or agents.
97. (Previously presented) The composition of claim 96, wherein the bioactive agent undergoes controlled release.
98. (Previously presented) The composition of claim 96, wherein the bioactive agent or agents are chosen from microbes, proteins, peptides, nucleic acids, hormones, drugs, antibiotics, enzymes, minerals, vitamins, antibodies, immunogens, microstructures, and nanostructures.
99. (Previously presented) The composition of claim 98, wherein the microbe is chosen from bacteria, yeast, and viruses.
100. (Previously presented) The composition of claim 99, wherein the microbe is chosen from *Bacillus* spp., *Lactobacillus* spp., *Lactococcus* spp., *Alteromonas* spp., *Carnobacterium* spp., *Vibrio* spp., *Pseudomonas* spp., *Streptococcus* spp., *Pseudoalteromonas* spp., *Saccharomyces* spp., *Phaffia* spp., *Pichia* spp., and *Kluyveromyces* spp.
101. (Withdrawn) The composition of claim 98, wherein the protein is chosen from somatostatin, somatostatin derivatives, growth hormones, prolactin, adrenocorticotrophic hormone (ACTH), melanocyte stimulating hormone (MSH), thyroid hormone releasing hormone (TRH), TRH salts, TRH derivatives, thyroid stimulating hormone (TSH), luteinizing hormone (LH), oxytocin, calcitonin, gastrin, secretin, pancreozymin, cholecystokinin, interleukins, thymopoietin, thymosin, thymostimulin, thymic factors, bombesin, neurotensin, lysozyme, protein synthesis stimulating peptides, vasoactive intestinal polypeptide (VIP), growth hormone releasing factor (GRF), and somatocrinin.
102. (Withdrawn) The composition of claim 98, wherein the antibiotic is chosen from gentamicin, tetracycline, oxytetracycline, doxycycline, ampicillin, ticarcillin, cephalothin, cephaloridine, cefotiam, cefsulodin, cefmenoxime, cefmetazole, cefazolin, cefotaxime, cefoperazone, ceftizoxime, moxolactam, latamoxef, thienamycin, sulfazecin, and azthreonam.

103. (Previously presented) The composition of claim 87, wherein the composition is further processed to provide a dry form.

104. (Previously presented) The composition of claim 87, wherein the composition is in a wet form.

105. (Previously presented) The composition of claim 87, wherein the particle size ranges from about 20 μm to about 150 μm .

106. (Cancelled)

107. (Previously presented) The composition of claim 87, further comprising one or more bioattractant.

108. (Previously presented) The composition of claim 87, further comprising nutrients.

109. (Previously presented) The composition of claim 87, wherein the animal is human.

110. (Previously presented) The composition of claim 87, wherein the animal is a domestic animal.

111. (Previously presented) The composition of claim 87, wherein the animal is an aquatic animal.

112. (Previously presented) The composition of claim 111, wherein the animal is a fish.

113. (Previously presented) The composition of claim 111, wherein the animal is a mollusk.

114. (Previously presented) The composition of claim 111, where in the animal is a shrimp.

115. (Previously presented) The composition of claim 111, wherein the animal is a rotifer.

116. (Previously presented) The composition of claim 111, wherein the animal is Artemia.

117. (Withdrawn) A method of producing an animal feed composition comprising a particle, wherein such method comprises:

(a) dissolving a starch in an alkaline solution,

- (b) adding an emulsifier to the starch and alkaline solution for a sufficient time to form a starch-emulsifier complex, wherein the starch-emulsifier complex is partially or completely insoluble;
- (c) neutralizing the solution comprising the formed starch-emulsifier complex;
- (d) adding alginate to the solution containing the starch-emulsifier complex;
- (e) adding a bioactive agent; and
- (f) atomizing the slurry resulting from (a)-(e), wherein the atomization produces a particle between about 10 μm and about 10,000 μm in size, and wherein the bioactive agent is microbound, viable, and bioavailable in a timed-release manner.

118. (Withdrawn) A method of delivery of a bioactive agent or agents comprising providing a particle to an animal, such particle comprising alginate, a partially or completely insoluble starch emulsifier complex, and one or more bioactive agent, wherein providing the particle delivers the particle to the animal.

119. (Withdrawn) A method of delivering a particle produced by the method of claim 117 to an aquatic animal comprising producing the particle and feeding the particle to an aquatic animal, wherein the bioactive agent has a bioactive effect on the animal in vivo.

120. (Withdrawn) The method of claim 117, wherein the bioactive agent is delivered to an aquatic animal.

121. (Previously presented) A particle comprising alginate and a starch-emulsifier complex, wherein the starch-emulsifier complex is partially or completely insoluble in water.

122. (Previously presented) The particle of claim 121 further comprising one or more bioactive agent.

123. (Previously presented) The composition of claim 99, wherein the microbe is chosen from *Bacillus licheniformis*, *Bacillus subtilis*, *L. bulgaricus*, *L. helveticus*, *L. plantarum*, *L. paracasei*, *L. casei*, *L. rhamnosus*, *L. lactis*, *A. media*, *C. divergens*, *V. alginolyticus*, *P. fluorescens*, *S. lactis*, *S. thermophilus*, *P. undina*, *S. cerevisiae*, *S. exiguus*, *P. rhodozoma*, *P. pastoris*, *K. aestuarii*, *K. marxianus*, and *K. yarrowii*.

Remarks

Claims 87-105 and 107-123 are pending.

Claims 1-86 and 106 are cancelled.

Claims 101, 102, and 117-120 are withdrawn.

Claims 87-100, 103-105, 107-116, and 121-123 are under current consideration.

Claim 87 is amended herein. Support for the amendment to claim 87 can be found in paragraphs [0037] and [0046] of the originally filed application.

Claim Rejections under 35 U.S.C. § 103(a)

1. Claims 87-100, 103-105, 107-116, and 121-123 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kürzinger (U.S. Patent No. 6,303,175; hereinafter, Kürzinger) in view of Tester (WO 99/53902; hereinafter, Tester), Nakatsuka (U.S. Patent No. 4,076,846; hereinafter, Nakatsuka), and Villamar (WO 02/00035; hereinafter, Villamar). Applicant traverses said rejection and submits that the proposed combination does not in any way establish a *prima facie* case of obviousness.

Initially, Applicant reiterates the arguments from the June 3, 2010 Response to the Office Action. In particular, Applicant submits that the Examiner used impermissible hindsight in an attempt to reconstruct the claimed invention; that Tester cannot be combined with Kürzinger because of explicit statements that teach against the combination; and that modifying Kürzinger with the teachings of Nakatsuka would make Kürzinger unsatisfactory for its intended purpose.

The Examiner acknowledges that “Kürzinger does not teach starch in combination with alginate explicitly.” See, paragraph 1 of the August 31, 2010 Office Action. Instead, the Examiner alleges that a skilled artisan would be motivated to select these components based on the prior art. As discussed in the previous response, Kürzinger provides a long list of synthetic, semisynthetic, and natural gel formers. The Examiner claims that only 34 specific compounds are disclosed but this ignores the broad categories of compounds that Kürzinger claims are suitable as gel formers.

For example, Kürzinger recites:

Natural gel formers or semi-synthetic gel formers or ones obtained in biotechnological ways are hydrocolloids of vegetable, animal or bacterial origin, such as e.g. polysaccharides, vegetable gums or collagens. These are obtained from natural algae, natural vegetable seed gums, natural vegetable juices, natural fruit extracts, biosynthetic gums, biosynthetically modified starches or cellulose materials or exocellular polysaccharides. See, col. 2, lines 17-24, of Kürzinger.

This list of broadly disclosed gel formers provides no guidance for one of skill in the art to combine alginate and a starch-emulsifier complex. As discussed in *In re. Kubin*, 90 USPQ2d 1417, 1423 (Fed. Cir. 2009), “where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness.” The Examiner also should not succumb to hindsight claims of obviousness based on Kürzinger because Kürzinger includes such a wide variety of speculative prior art possibilities as to provide no teaching to combine any of them. As recited in MPEP §2142, “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” The Examiner recognized this limitation of Kürzinger and searched for secondary art that could potentially motivate one of skill in the art to combine alginate with a starch-emulsifier complex. Applicant submits that the need to search for prior art motivating the combination of two compounds briefly mentioned in Kürzinger is itself a form of impermissible hindsight. Without the Applicant’s invention as a roadmap, one of skill in the art reading Kürzinger would have no teaching, suggestion, or motivation to combine alginate with a starch-emulsifier complex.

Nevertheless, the Examiner stated that “Tester specifically motivates the selection of starch and alginate.” See, page 11, lines 2-3, of the August 31, 2010 Office Action. The Examiner attempted to support this allegation by stating that “Tester teaches that ‘sodium alginate is a relatively cheap and effective gelling agent. It is symbiotic with starch and forms a coherent matrix.’” See, paragraph 2 of the August 31, 2010 Office Action. However, immediately after the portion of Tester quoted by the Examiner, Tester recites:

Polygalacturonic acid (demethylated pectin) is equally freely available, but tends to be more expensive than alginic acid. However, **alginic acids have some questionable nutritional attributes because they may have picked up heavy metals from seawater during biosynthesis.** See, page 48, lines 17-22, of Tester (emphasis added).

Clearly, one of skill in the art reading that alginic acids have questionable nutritional attributes would not choose to combine alginic acids with starch for use as an animal feed.¹ As recognized by the Examiner, “the ordinary artisan would readily envisage the possibility of [administration of the feed taught by Kürzinger] to humans, particularly in light of Nakatsuka’s teaching that the components of the composition should have no harmful effect on the human body.” See, paragraph 12 of the August 31, 2010 Office Action. One of skill in the art, reading that alginic acid potentially contains heavy metal contaminants, would not combine it with starch to form an animal feed knowing that heavy metal bioaccumulation could result in toxicity to humans.

Thus, Applicant submits that Tester teaches away from combining alginate and a starch-emulsifier complex in an animal feed composition. MPEP §2145XD1 recites that “[a] prior art reference that ‘teaches away’ from the claimed invention is a significant factor to be considered in determining obviousness.” Additionally, MPEP §2145XD2 recites that “[i]t is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).” Here, Tester clearly teaches away from the claimed invention and from Kürzinger and Nakatsuka when it recites that alginic acid has questionable nutritional attributes. Thus, Tester cannot be applied against the instant invention and cannot be combined with Kürzinger or Nakatsuka.

Also, modifying Kürzinger with the teachings of Nakatsuka would make Kürzinger unsatisfactory for its intended purpose. As discussed in the previous response, Kürzinger teaches an insoluble feed product and Nakatsuka teaches a soluble feed product. The Examiner rejected this argument and stated that “Nakatsuka and Tester are merely relied upon for motivation and teachings of certain amounts of components, about which Kürzinger is silent.” See, page 13, lines 4-5, of the August 31, 2010 Office Action. **This is improper.**

As recited by MPEP §2141.02VI, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).” (emphasis in original). Thus, both Kürzinger and Nakatsuka must be considered in their entirety. When

¹ See also, page 46, lines 8-12, of Tester, reciting that “pectin is preferred in some formulations as **alginic acid** is not necessarily a flavoured [sic] nutrient (particularly in health care products) as it **potentially contains contaminants** associated with the growth of kelp in the sea,” and page 58, lines 30-34, of Tester, reciting “beads can be made using 50% starch, which might be desirable in the context of the better enzyme digestibility and **safety of starch, relative to alginic acid.**” (emphasis added).

considered in their entirety for what they would teach one of skill in the art, it is clear that modifying Kürzinger with the teachings of Nakatsuka would make Kürzinger unsatisfactory for its intended use.

Specifically, Kürzinger indicates the necessity of an insoluble feed product by reciting:

It is a prerequisite that, by suitable choice of one or more gel formers, under certain conditions in combination with other nutritional components, **the consistency of the feed is so adjusted that the fish**, because of the soft property, **can bite off**, without problems, **mouth-sized pieces** and subsequently swallow. See, col. 3, lines 38-44, of Kürzinger (emphasis added).

In contrast, Nakatsuka emphasizes that the object of the invention is to provide a soluble molding composition by reciting:

An object of this invention is to provide a so-called water soluble, edible, thermoplastic molding composition comprising an alkali metal or alkaline earth metal salt of a protein material, a starch material, water, and organic low-molecular-weight plasticizer, and a lubricant, all of these components being edible. See, col. 1, lines 16-21, of Nakatsuka (emphasis added).

Modifying the compound of Kürzinger, which must be insoluble so that fish are able to bite off mouth-sized pieces, with the teachings of Nakatsuka, which provides a water-soluble molding composition as an object of the invention, would clearly make Kürzinger unsatisfactory for its intended purpose. As recited in MPEP §2143.01V, “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” Modifying the feed product of Kürzinger with the teaching of Nakatsuka, which has as an object of the invention a soluble composition, would make the feed of Kürzinger unsatisfactory for its intended use because fish would not be able to bite off mouth-sized pieces. Thus, there is no suggestion or motivation to combine Kürzinger with Nakatsuka.

Villamar does not cure the deficiencies of Kürzinger, Tester, and Nakatsuka. Villamar is directed to a bioactive food complex product, method for preparing a bioactive food complex product, and method for controlling disease. Notably, Villamar does not teach or suggest the inclusion of starch in the Villamar food complex, and as such, Villamar completely fails to teach the starch-emulsifier complex claimed herein. Accordingly, Villamar does not cure the deficiencies of Kürzinger, Tester, and Nakatsuka.

Finally, in an attempt to move the application towards allowance, Claim 87 has been amended to recite:

“An animal feed composition comprising a particle ranging in size from the about 100 μ m to about 1 cm, **wherein the particle is formulated to begin dissolving within the pH range of an animal’s foregut,** wherein ~~such~~ the particle comprises alginate and a starch-emulsifier complex, wherein the alginate comprises from about 0.5 to about 2.0 percent by wet weight of the particle, the emulsifier comprises a ratio to the starch from about 1:10 to about 10:1, and the starch-emulsifier complex is partially or completely insoluble in water.”

Applicant submits that Kürzinger, Tester, Nakatsuka, and Villamar do not teach a composition comprising a particle, wherein the particle is formulated to begin dissolving within the pH range of an animal’s foregut. Even if the cited references were inappropriately combined, the combination of Kürzinger, Tester, Nakatsuka, and Villamar fails to teach the invention claimed here. Therefore, the Examiner has failed to present a *prima facie* case of obviousness in view of Kürzinger, Tester, Nakatsuka, and Villamar.

In light of the foregoing discussion and the fact that all of claimed limitations are not disclosed or suggested by the cited combination and/or the proposed combination is taught against by the prior art or will render the invention of Kürzinger unsatisfactory for its intended use, it is clear that the Office has not met its burden of establishing a *prima facie* case of obviousness. Reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection of claims 87-100, 103-105, 107-116, and 121-123 is hereby requested

Rejoinder of Method Claims

Applicant requests that when the product claims of the present invention are found patentable, all pending method of making and using claims are examined through the rejoinder procedure in accordance with MPEP §821.04. Rejoinder is proper when an application as originally filed discloses a product and the process for making and/or using such product, and only the claims directed to the product are presented for examination, when a product claim is found allowable, Applicant may present claims directed to the process of making and/or using the patentable product for examination through rejoinder procedure in accordance with MPEP §821.04, provided that the process claims depend from or include all the limitations of the allowed product claims.

Fees Payable

No fees are believed due at this time. If any fee is found due for entry of this amendment, the Commissioner is authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen.

Conclusion

Applicant has satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Orwig, reconsider the patentability of all pending claims, in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Orwig is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,

Date: November 30, 2010

/mariannefuierer/

Marianne Fuierer
Reg. No. 39,983
Attorney for Applicant

Date: November 30, 2010

/andrewgerschutz/

Andrew D. Gerschutz
Reg. No. 65,529
Attorney for Applicant

Moore & Van Allen, PLLC
Telephone: (919) 286-8000
Facsimile: (919) 286-8199